IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
ORANGEBURG DIVISION

Mary Nimmons Plaintiff, v. Johnson & Johnson, Inc. and Ethicon, Inc. Defendants.	**COMPLAINT** **(JURY TRIAL DEMANDED)** **CASE NO.** 5:17-01551-JMC

COMES NOW, Plaintiff, Mary Nimmons (Hereinafter "Plaintiff"), by and through undersigned counsel, and brings this action against Defendants Ethicon, Inc. (hereinafter "Ethicon") and Johnson & Johnson (hereinafter "J&J") (collectively, hereinafter "Defendants'), and allege as follows:

PARTIES

1. Plaintiff Mary Nimmons is, and was, at all relevant times, a citizen and resident of Bamberg County, South Carolina.

2. Defendant Johnson & Johnson (hereinafter referred to as "J&J") is a corporation incorporated in New Jersey, and per its website, the world's largest and most diverse medical device and diagnostics company, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey, 08933. Defendant J&J is a citizen of New Jersey and subject to the jurisdiction of this Court by its placement of products into the stream of commerce that are sold directly to consumers in South Carolina, specifically Orangeburg County, The Regional Medical Center ("TRMC") and subsequently to Plaintiff. On information and belief,

TRMC purchases medical devices, specifically the product at issue in this litigation, directly from Defendant J&J and Defendant Ethicon, Inc.

3. Defendant J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its products, including but not limited to its hernia repair mesh products. Within J&J there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution and sale of the hernia repair mesh products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc.

4. Defendant Ethicon, Inc. (hereinafter referred to as "Ethicon") is a wholly owned subsidiary of Defendant J&J. Defendant Ethicon is a corporation incorporated in the State of New Jersey with its principal place of business in Route 22 West, Somerville, New Jersey, with its registered agent being Johnson & Johnson, Inc, located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Ethicon is a citizen of New Jersey subject to the jurisdiction of this Court by its placement of products into the stream of commerce that are sold directly to consumers in South Carolina, specifically Orangeburg County, TRMC and subsequently to Plaintiff. Ethicon is not registered to transact business within the State of South Carolina, but may be served through its chief executive officer, Alex Gorsky, at One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

5. Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including the

ETHICON PHYSIOMESH™ Flexible Composite Mesh (Oval 20cm x 25cm) device, Product Code PHY2025V (hereinafter "Physiomesh" and/or "product").

6. J&J, directly and/or through the actions of Ethicon, Inc., has at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of Physiomesh.

7. Defendants collectively are individually, jointly and severally liable to Plaintiff Mary Nimmons for damages suffered by Plaintiff Mary Nimmons arising from Defendants Ethicon and J&J's design, manufacture, marketing, labeling, distribution, sale, placement, and implantation of its defective Physiomesh product at issue in the instant action, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

8. Defendants are vicariously liable for the acts and/or omissions of its employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

JURISDICTION AND VENUE

9. Plaintiff re-incorporates herein the above paragraphs 1 through 8 of Plaintiff's Complaint as if fully stated herein verbatim.

10. This is an action for monetary damages in excess of Seventy-Five Thousand Dollars ($75,000.00).

11. The parties are citizens of different states and subject matter jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1332.

12. This Court has personal jurisdiction over each of Defendants J&J and Ethicon. Defendants transact business within the State of South Carolina, and Defendants committed tortious acts and

omissions in South Carolina. Defendants' tortious acts and omissions caused injury to Plaintiff in the State of South Carolina. Defendants have purposefully engaged in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, medical devices, including Physiomesh mesh products, in South Carolina, for which they derived significant and regular income. Defendants reasonably expected that that their defective Physiomesh products would be sold and implanted in patients residing in South Carolina. Furthermore, Defendants J&J and Ethicon have an official product distributor in the State of South Carolina as evidenced in the *Johnson & Johnson Authorized Distributor Master List* ***(Exhibit A)*** provided by Defendants online, namely Southern Anesthesia & Surgical, Inc., Distributor Number 1237145, headquartered in West Columbia, South Carolina and specifically distributing "Ethicon Products," including "Sutures, DERMABOND™, Mesh and Drains" and "Johnson & Johnson Wound Management," including "BioSurgery and BIOPATCH®."

13. Venue is proper in this Honorable Court.

FACTS COMMON TO ALL COUNTS

14. Plaintiff re-incorporates herein the above paragraphs 1 through 13 of Plaintiff's Complaint as if fully stated herein verbatim.

15. On October 4, 2010, Defendants J&J and Ethicon, identified as a worldwide leader in surgical care, announced the launch of ETHICON PHYSIOMESH™ Flexible Composite Mesh, a surgical device to "provide secure mesh fixation and address patient comfort and surgeon ease-of-use in laparoscopic (minimally invasive) hernia repair procedures" which had been recently granted 510(k) market clearance by the U.S. Food and Drug Administration (FDA). See ***Exhibit B***, Johnson & Johnson Press Release: *Ethicon, Inc. Introduces Two Innovative Devices for Minimally Invasive Hernia Repair during American College of Surgeons (ACS) Annual Meeting*.

Defendants J&J and Ethicon described the Physiomesh as "a lightweight and partially-absorbable polypropylene mesh" that "stretches to closely match the abdominal wall" and "allows for excellent parietal tissue integration, while the poliglecaprone 25 transparent film serves as a tissue separation barrier to minimize visceral attachments." The release also contained the opinions of a practicing surgeon that was a "paid consultant" to Defendant Ethicon.

16. In its submission to the FDA in March 2010, Defendant Ethicon identified the Physiomesh as follows:

> *ETHICON PHYSIOMESH™, Flexible Composite Mesh, is a sterile, low profile, flexible composite mesh designed for the repair of hernias and other fascial deficiencies. The mesh product is composed of a nonabsorbable, microporous polypropylene mesh laminated between two undyed poliglecaprone-25 films. An undyed polydioxanone film provides the bond between the poliglecaprone-25 film and polypropylene mesh. The polypropylene component is constructed of knitted filaments of extruded polypropylene. An additional dyed polydioxanone film marker has been added for orientation purposes.*

See ***Exhibit C***, *Ethicon 510(k) Summary*. Defendant Ethicon identified its medical device as being substantially equivalent to three other products on the market, which was misleading, to be used "for the repair of hernias and other fascial deficiencies that require the addition of a reinforcing or bridging material."

17. Defendant Ethicon further provided "Performance Data" in its submission to the FDA, stating:

> *ETHICON PHYSIOMESH™, Flexible Composite Mesh underwent a comprehensive bench, an animal testing program and passed all intended criteria in accordance with appropriate test protocols and standards. During bench testing the device was subject to testing such as device thickness, pose size, burst strength, device weight, tensile strength, device stiffness, suture pullout strength, burst strength and tear resistance. Additionally, invitro and in-vivo testing was provided showing that the device performed as intended.*

Defendant reported an "Overall Performance Conclusion" that the Physiomesh met all testing criteria demonstrated substantial equivalence to its predicate devices and did not raise any new questions of safety or effectiveness.

18. The FDA granted 510(k) clearance to Defendants for the Physiomesh. However, that clearance did not equate to a finding that the Physiomesh is safe for physical implantation into consumers nor does it create a limitation of liability for the device being defective when it consistently fails. Additionally, the FDA's Department of Health & Human Services warned Defendant Ethicon that "[w]e remind you; however, that device labeling must be *truthful and not misleading*." ***(Exhibit D)*** *(Emphasis Added).*

19. Under the 510(k) program, there are no requirements for safety and efficacy, and Defendants J&J and Ethicon, knowing that fact, took insufficient steps to ensure their product was safe and bio-compatible with the human body prior to marketing the product.

20. In 2011, the Institute of Medicine provided that the 510(k) program was "fatally flawed" and should be abolished; the U.S. Government Accountability Office having criticized the FDA for failing to recall products and regulate high-risk devices approved under 510(k) – the same approval process that allowed metal-on-metal hips to be marketed and defibrillator leads, which were both found to be defective on injuring patient consumers post-510(k) approval. Approval through the 510(k) program does not preempt nor prohibit a finding that a medical product is defective.

21. By 2012, reports from mandatory reporters (such as device users) and voluntary reporters (such as health care professionals, patients, and consumers) regarding failures of the Physiomesh began to flood into the FDA, many recorded into the FDA's Manufacturer and User Facility Device

Experience ("MAUDE") Database. Reports were filled with failures such as those outlined herein, which resulted in significant injuries to customers implanted with the device.

22. On or about October 30, 2015, Plaintiff Mary Nimmons presented to TRMC for pain associated with a periumbilical hernia that had increased in size and pain over the previous three (3) months. At that time, Plaintiff presented with no nausea, no vomiting, no diarrhea, no constipation, no hematemesis, no abdominal distention, no loss of appetite, and no change in her bowel habits. She was diagnosed with a ventral hernia without obstruction or gangrene.

23. On or about November 10, 2015, just two (2) days before her 64th birthday and at the suggestion of her medical providers, Plaintiff Mary Nimmons underwent a laparoscopic ventral hernia repair. During the surgery, which was performed by Kimberly Miller-Hammond, M.D. at TRMC in Orangeburg, South Carolina, Plaintiff was implanted with Defendants J&J and Ethicon's *ETHICON PHYSIOMESH™ Flexible Composite Mesh (Oval 20cm x 25cm) device, Product Code PHY2025V*. Plaintiff was discharged home the same day after surgery and incurred in excess of $40,000.00 in medical expenses for the same, including the cost of Defendant J&J and Ethicon's defective Physiomesh device.

24. Defendants J&J and Ethicon manufactured, produced, sold, and/or distributed the Physiomesh device to Plaintiff, through her doctors and TRMC, to be used for treatment of hernia repair; the specific purpose for which Plaintiff underwent the procedure and installation of Defendants' Physiomesh.

25. Plaintiff's condition was not remedied by the procedure on November 10, 2015. In fact, her condition became steadily worse with persistent abdominal pain, diminished bowel motility and bowel obstruction.

26. On November 17, 2015, Plaintiff was re-admitted to TRMC with severe nausea, vomiting, abdominal cramping and abdominal distention, which began five (5) days prior on November 12, 2015. Medical imaging scans taken revealed hernia recurrence, specifically a paraumbilical hernia containing soft tissue, possibly bowel, and it was noted that free fluid was seen within Plaintiff's pelvis in addition to seroma. At this time, a paraumbilical hernia defect was noted containing fluid along with postoperative seroma. Plaintiff would not be discharged from TRMC until November 25, 2015, incurring over $50,000.00 in medical expenses during the course of her nine (9) day hospital stay.

27. After months of continued and worsening pain, discomfort and sickness, including extended hospital visits that began less than one week after her original November 10, 2015 laparoscopic ventral hernia repair with TRMC implanting Defendants J&J and Ethicon's defective Physiomesh device, on or about October 11, 2016, Plaintiff Mary Nimmons underwent surgery at TRMC for severe hernia recurrence, a surgery which occurred nine (9) days after the untimely death of her husband. The defective Physiomesh device had not completely incorporated into the abdominal wall and had begun to disintegrate, with a recurrent hernia noted in areas where the mesh had torn and disintegrated. Portions of Plaintiff's intestines were protruding through the broken-down portions of the mesh, and Plaintiff suffered an intestinal obstruction. Plaintiff underwent a prolonged surgical procedure to attempt to remove the mesh from her abdomen and intestines and to remove the mesh that failed to incorporate into the abdominal facsia.

28. Plaintiff, who was and remains retired from the workforce, incurred in excess of $40,000.00 in medical expenses for the same-day outpatient surgery at TRMC to repair severe hernia recurrence and complications resulting from Defendants J&J and Ethicon's defective Physiomesh device – more than the median household annual income of $34,218.00 and more than

$22,000.00 above the per capita income for a family in Orangeburg County according to the United States Census Bureau.

29. Defendants J&J and Ethicon were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of Physiomesh, including providing the warnings and instructions concerning the product.

30. Among the intended purposes for which Defendants J&J and Ethicon designed, manufactured and sold Physiomesh was use by surgeons for hernia repair surgeries, the purpose for which the Physiomesh was implanted in Plaintiff Mary Nimmons.

31. Defendants represented to Plaintiff and Plaintiff's treating physicians that Physiomesh was a safe and effective product for hernia repair.

32. Plaintiff and Plaintiff's physicians would not have agreed to the implantation of the Physiomesh device had she known of the potential complications.

33. Defendants J&J and Ethicon's Physiomesh was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the Physiomesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; inadequate or failure of incorporation/ingrowth; migration; scarification; deformation of mesh; improper wound healing; excessive and chronic inflammation; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tissue damage and/or death; and other complications.

34. Defendants should have been "truthful and not misleading" in their labeling of the Physiomesh product so as to warn the public, including Plaintiff, and medical providers, including Plaintiff's treating physicians, of the risks associated with Physiomesh implantation.

35. Physiomesh has a unique design incorporating five (5) distinct layers: two layers of polyglecaprone-25 ("Monocryl") film covering two underlying layers of polydioxanone film ("PDS"), which in turn coat a polypropylene mesh. This design is not used in any other hernia repair product sold in the United States. The multi-layer coating was represented and promoted by the Defendants to prevent or minimize adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the multi-layer coating prevented adequate incorporation of the mesh into the body and caused or contributed to an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction including migration and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing.

36. When affixed to the body's tissue, the impermeable multi-layer coating of the Physiomesh prevents fluid escape, which leads to seroma formation, and which in turn can cause infection, abscess formation and other complications.

37. The multi-layer coating provides a breeding ground for bacteria in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate.

38. The multi-layer coating of Defendants J&J and Ethicon's Physiomesh is cytotoxic, immunogenic, and not biocompatible with humans, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

39. Defendants J&J and Ethicon knew or should have known of the cytotoxic and immunogenic properties of the multi-layer coating of the Physiomesh prior to introducing it into the stream of commerce.

40. The polypropylene mesh portion of the Physiomesh was insufficient to withstand normal abdominal forces, which result in recurrent hernia formation and/or rupture and deformation of the mesh itself.

41. When the multi-layer coating of the Physiomesh is disrupted and/or degrades, the "naked" polypropylene mesh is exposed to the adjoining tissue and viscera, and can become adhered to organs, and cause damage to organs, and potentiate fistula formation.

42. These manufacturing and design defects associated with the Physiomesh were directly and proximately related to the injuries suffered by Plaintiff Mary Nimmons.

43. Defendants J&J and Ethicon made public statements in the form of written Product descriptions, Product labels, promotional materials and other materials that asserted that implanting the Physiomesh in patients was safe and would not cause harm to patients.

44. The statements referenced in the above-Paragraph were made with the intent that medical professionals and members of the public would rely upon them, with the intent that members of the public would pay for the Physiomesh and that the Physiomesh would be implanted in patients.

45. When Defendants J&J and Ethicon made these statements, they knew that the statements were inaccurate. Alternatively, they should have known that the statements were inaccurate.

46. Representatives of Defendants J&J and Ethicon also made statements to numerous individuals, including medical professionals, that implanting the Physiomesh in patients was safe and would not cause harm to patients. When Defendants' representatives made these statements,

they knew that the statements were inaccurate. Alternatively, they should have known that these statements were inaccurate.

47. Defendants J&J and Ethicon knowingly and deliberately made material representations to the United States Food and Drug Administration concerning the design, manufacture, safety, and efficacy of the Physiomesh. Defendants also failed to abide by the FDA's instruction that Physiomesh labeling need be "truthful and not misleading."

48. Before Plaintiff suffered the injuries complained of herein, Defendants were on notice of numerous bodily injuries caused by the Physiomesh, and based thereon, Defendants knew or should have known that the Physiomesh caused an unreasonably high rate of failure and injury to patients implanted with the Physiomesh. Had Defendants timely acted on their actual and/or constructive knowledge of the defective nature of their Physiomesh product, Plaintiff would have not been injured by the surgical implantation of the defective product by an unknowing medical professional on or about November 10, 2015.

49. Defendants J&J and Ethicon have sold thousands of Physiomesh products across the country, including in South Carolina.

50. Even though Defendants knew or should have known that the Physiomesh created a foreseeable and unreasonable risk of harm to those patients in which it was implanted, Defendants J&J and Ethicon continued to market the Physiomesh in the United States, including South Carolina, and physicians at TRMC continued to implant the Physiomesh in its patients, including Plaintiff.

51. On May 25, 2016, Defendants J&J and Ethicon issued an "Urgent Field Safety Notice" for all product codes of *ETHICON PHYSIOMESH™ Flexible Composite Mesh* to "Operating Room Supervisors, Materials Management Personnel, and Chief[s] of Surgery." ***(Exhibit E)***. Despite

admitting that "[t]he recurrence/reoperation rates (respectively) after **laparoscopic** ventral hernia repair using ETHICON PHYSIOMESH™ Composite Mesh were higher than" average and despite direct evidence and available medical and product data overwhelmingly evidencing a defective product, Defendants have yet to willingly acknowledge that their Physiomesh product is defective, instead misleadingly indicating that "Ethicon believes the higher rates [of recurrence/reoperation] to be a multifactorial issue (including possible product characteristics, operative and patient factors), but has not been able to fully characterize these factors."

52. Plaintiff Mary Nimmons nor her physicians were adequately warned or informed by Defendants of the defective and dangerous nature of Physiomesh. Moreover, Plaintiff Mary Nimmons nor her physicians were adequately warned or informed by Defendants of the risks associated with the Physiomesh or the frequency, severity, or duration of such risks.

53. The Physiomesh implanted in Plaintiff Mary Nimmons failed to reasonably perform as intended. The mesh failed, caused serious injury and portions of the mesh had to be surgically removed via invasive surgery, and necessitated additional invasive surgery to repair the hernia that the Physiomesh was initially implanted to treat.

54. Plaintiff Mary Nimmons's severe adverse reaction, and the necessity for surgical removal of the Physiomesh, directly and proximately resulted from the defective and dangerous condition of the product and Defendants' defective and inadequate warnings about the risks associated with the product, and the frequency, severity and duration of such risks.

55. Plaintiff Mary Nimmons has suffered, and will continue to suffer, both physical injury and pain and mental anguish, permanent and severe scarring and disfigurement, and has incurred substantial medical bills and other expenses, resulting from the defective and dangerous condition

of the product and from Defendants' defective and inadequate warnings about the risks associated with the product.

56. Defendant J&J and Ethicon failed to adequately test and study the Physiomesh to determine and ensure that the product was safe and effective prior to releasing the product for sale for permanent human implantation, and Defendants continued to manufacture and sell Physiomesh after obtaining knowledge and information that the product was defective and unreasonably unsafe. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the Physiomesh, Defendants developed, designed and sold Physiomesh, and continue to do so, because the Physiomesh has a significantly higher profit margin than other hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous and defective Physiomesh, including the risk of failure and serious injury, such as suffered by Plaintiff. Defendants willfully and recklessly failed to avoid those consequences, and in doing so, Defendants acted willfully, recklessly, wantonly, maliciously, and in a grossly negligent manner with regards to the safety of those persons who might foreseeably have been harmed by the Physiomesh product, including Plaintiff, justifying the imposition of punitive damages.

COUNT I
Strict Product Liability: Defective Design As to Defendants Johnson & Johnson and Ethicon, Inc.

57. Plaintiff re-incorporates herein the above paragraphs 1 through 56 of Plaintiff's Complaint as if fully stated herein verbatim.

58. At the time the Physiomesh that was implanted in Plaintiff Mary Nimmons's body, the product was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and

Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

59. Defendants expected and intended the Physiomesh product to reach users such as Plaintiff in the condition in which the product was sold.

60. The implantation of Physiomesh in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

61. The risks of the Physiomesh design significantly outweigh any benefits that Defendants contend could be associated with the product's design. The multi-layer coating, which is not used in any other hernia mesh product sold in the United States, prevents tissue from incorporating into the mesh, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The impermeable multi-layer coating leads to seroma formation, and provides a breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response.

62. The multi-layer coating of the Physiomesh, which was marketed, promoted and intended as a barrier against adhesion to the internal organs, was only temporary; it was expected and intended to degrade over time inside the body. Thus, this coating prevented tissue ingrowth in the short term, and degraded in the long-term, eventually leaving the "naked" polypropylene mesh exposed to the internal viscera and tissues. The degradation of this multi-layer coating caused or exacerbated an intense inflammatory and foreign body reaction. Once exposed to the viscera, the polypropylene mesh will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the multi-layer coating (to prevent adhesion to

the internal viscera and organs) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

63. The polypropylene mesh within the defective multi-layer coating of the Physiomesh was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the Physiomesh. When implanted adjacent to the intestines and other internal organs, as Defendants intended for Physiomesh, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

64. The polypropylene mesh used in the Physiomesh device was insufficient in strength to withstand the internal forces of the abdomen after implantation, which made the device susceptible to rupture and/or deformation, as occurred with the Physiomesh implanted in Plaintiff Mary Nimmons.

65. The appropriate treatment for complications associated with Physiomesh involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to the patient.

66. Physiomesh was designed and intended for intraperitoneal implantation, which involved the product being implanted in contact with the intestines and/or other internal organs, which unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.

67. At the time the Physiomesh was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries she suffered.

68. The Physiomesh product cost significantly more than competitive products because of its unique multi-layer coating, even though the multi-layer coating provided no benefit to consumers, and increased the risks to patients implanted with these devices.

69. The Physiomesh implanted in Plaintiff failed to reasonably perform as intended, and had to be surgically removed necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus provided no benefit to her.

70. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff suffered injuries and damages as summarized herein.

COUNT II
Strict Product Liability: Failure to Warn As to Defendants Johnson & Johnson and Ethicon, Inc.

71. Plaintiff re-incorporates herein the above paragraphs 1 through 70 of Plaintiff's Complaint as if fully stated herein verbatim.

72. At the time the Physiomesh that was implanted in Plaintiff's body, the warnings and instructions provided by Defendants for the Physiomesh were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

73. Defendants failed to provide such warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Physiomesh or to those patients who had been implanted with the Physiomesh, concerning the following risks, of which Defendants had actual or constructive knowledge at the time the Physiomesh left the Defendants' control:

a. The high failure rate of the Physiomesh;

b. The high rate of infections and abscesses caused by the Physiomesh;

c. The high rate of abdominal erosions and extrusions caused by the Physiomesh;

d. The high rate of chronic pain caused by the Physiomesh;

e. The high rate of migration of the Physiomesh;

f. The high rate of bowel obstruction caused by the Physiomesh;

g. The high rate of diminished bowel motility caused by the Physiomesh;

h. The high rate of corrective surgeries caused by the defective Physiomesh;

i. The high rate of patient injuries caused by the Physiomesh's migration, decomposition, infections, abscesses, erosion, extrusion, adhesion to bodily organs, and interference with normal bodily functions.

74. Defendants expected and intended the Physiomesh product to reach users such as Plaintiff in the condition in which the product was sold.

75. Plaintiff and her physicians were unaware of the defects and dangers of Physiomesh, and were unaware of the frequency, severity and duration of the defects and risks associated with the Physiomesh.

76. The Defendants' Instructions for Use provided with the Physiomesh expressly understates and misstates the risks known to be associated specifically with the Physiomesh by stating that "Potential adverse reactions are those typically associated with surgically implantable materials." No other surgical mesh sold in the United States – and no other "surgically implantable material" – suffers the same serious design flaws as Physiomesh. No other device or material contains the dangerous and defective multi-layer coating, which itself causes or increases the risks of numerous complications, including prevention of incorporation, increased risk of seroma formation, immunologic response, increased risk for infection, and increased inflammatory reaction and foreign body response. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Physiomesh.

77. The Defendants' Instructions for Use for the Physiomesh failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or should have known were

associated with the Physiomesh, including the risks of the product's inhibition of tissue incorporation, pain, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, shrinkage/contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, intestinal obstruction, failure of repair/hernia recurrence, hernia incarceration or strangulation, or rupture of the mesh.

78. Defendants failed to adequately train or warn Plaintiff or her physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

79. Defendants failed to adequately warn Plaintiff or her physicians that the necessary surgical removal of the Physiomesh in the event of complications would leave the hernia unrepaired, and would necessitate further medical treatment to attempt to repair the same hernia that the failed Physiomesh was intended to treat.

80. Defendants represented to physicians, including Plaintiff's physician, that the multi-layer coating would prevent or reduce adhesion, and expressly intended for the Physiomesh to be implanted in contact with the intestines and internal organs and marketed and promoted the product for said purpose. Defendants failed to warn physicians that the multi-layer coating prevented tissue ingrowth, which is the desired biologic response to an implantable mesh device. Defendants failed to warn physicians that the multi-layer coating was only temporary and therefore at best would provide only a temporary adhesion barrier, and when the coating inevitably degraded, the exposed polypropylene would become adhered to the organs or tissue.

81. With respect to the complications that were listed in the Defendants' warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those

complications, even though the complications associated with Physiomesh were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

82. If Plaintiff and/or her physicians had been properly warned of the defects and dangers of Physiomesh, and of the frequency, severity and duration of the risks associated with the Physiomesh, Plaintiff would not have consented to allow the Physiomesh to be implanted in her body.

83. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized herein.

COUNT III
Strict Product Liability: Defective Manufacture As to Defendants Johnson & Johnson and Ethicon, Inc.

84. Plaintiff re-incorporates herein the above paragraphs 1 through 84 of Plaintiff's Complaint as if fully stated herein verbatim.

85. One or more of the defects in the Physiomesh is the result of improper or incorrect manufacturing processes that result in the Physiomesh as manufactured deviating from its intended design.

86. The defects caused by manufacturing defect rendered the Physiomesh unreasonably dangerous to consumers and to Plaintiff.

87. The defects in the Physiomesh implanted in Plaintiff existed from its manufacture, therefore, the defects were present when it left the possession and control of Defendants.

88. As a direct and proximate result of the defective manufacture of the Physiomesh, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT IV
Strict Product Liability: Lack of Product Durability As to Defendants Johnson & Johnson and Ethicon, Inc

89. Plaintiff re-incorporates herein the above paragraphs 1 through 88 of Plaintiff's Complaint as if fully stated herein verbatim.

90. Defendants intended the Physiomesh product to be implanted within the human body, including Plaintiff's, and knew or should have known such placement was permanent in nature.

91. Defendants knew or should have known that product durability when placed within the confounds of the human body is of the utmost importance as should any problems with the product's durability arise, invasive surgery must be done on a patient, including Plaintiff, to address the complications.

92. The durability defects in the Physiomesh implanted in Plaintiff existed from its manufacture, therefore, these durability defects too were present when it left the possession and control of Defendants.

93. The Physiomesh implanted in Plaintiff suffered durability problems contributing to the failure of the product once implanted and contributed to the necessity of a subsequent hernia recurrence surgery to remove the failed product.

94. As a direct and proximate result of the defective manufacture of the Physiomesh with regards to its durability, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT V
Negligence As to Defendants Johnson & Johnson and Ethicon, Inc.

95. Plaintiff re-incorporates herein the above paragraphs 1 through 94 of Plaintiff's Complaint as if fully stated herein verbatim.

96. Defendants had a duty to Plaintiff and the public to exercise reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training, and preparing written instructions and warnings for Physiomesh, but failed to do so.

97. Defendants failed to exercise ordinary and reasonable care in designing, manufacturing, testing, marketing, labeling, packaging, selling and/or distributing the Physiomesh and Defendants negligently failed to provide adequate warnings and instructions to Plaintiff and/or her physicians regarding the Physiomesh. Further, Defendants failed to exercise ordinary and reasonable care by failing to warn patients and their physicians of the unreasonably high rate of injury to patients and unreasonably high rate of corrective surgeries required to treat Physiomesh related complications.

98. Defendants knew, or in the exercise of reasonable care should have known, that Physiomesh was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom Physiomesh was implanted. Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the Physiomesh.

99. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training and preparing written instructions and warnings for Physiomesh, Plaintiffs suffered injuries and damages as summarized herein.

COUNT VI
Breach of Express Warrant As to Defendants Johnson & Johnson and Ethicon, Inc

100. Plaintiff re-incorporates herein the above paragraphs 1 through 99 of Plaintiff's Complaint as if fully stated herein verbatim.

101. Defendants expressly represented to Plaintiff and her medical providers that the Physiomesh was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

102. Physiomesh does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries, including but not limited to the risk of bowel adhesions, diminished bowel motility, bowel obstruction, chronic abdominal pain, and a high rate of corrective surgeries required to treat Physiomesh related complications.

103. At all relevant times, the Phyiomesh did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

104. Plaintiff and other consumers relied upon Defendants' express warranties.

105. As a direct and proximate result of Defendants' conduct, Plaintiff suffered medical complications that included but were not limited to pain and suffering, disability, permanent scarring, mental anguish, loss of capacity for enjoyment of life, lost wages, loss of net accumulations, expenses of hospitalization, extensive medical and nursing care and treatment in the past and in the future, and aggravations of pre-existing medical conditions.

COUNT VII
Breach of Implied Warranty of Fitness For a Particular Purpose/Merchantibility As to Defendants Johnson & Johnson and Ethicon, Inc

106. Plaintiff re-incorporates herein the above paragraphs 1 through 105 of Plaintiff's Complaint as if fully stated herein verbatim.

107. Defendants designed, manufactured, tested, trained, marketed, promoted, packaged, labeled, and/or sold the Physiomesh product.

108. At all relevant times, Defendants knew of the use for which the Physiomesh product was intended and impliedly warranted the Physiomesh to be of merchantable quality and safe and fit for such use.

109. Defendants were aware that consumers, including Plaintiff would use the Physiomesh for the treatment and repair of hernias.

110. Plaintiff and other consumers reasonably relied upon the judgment and sensibility of Defendants to sell the Physiomesh only if it was indeed of merchantable quality and safe and fit for its intended use.

111. Defendants breached their implied warranty to consumers, including Plaintiff; the Physiomesh was not of merchantable quality or safe and fit for its intended use.

112. Consumers, including Plaintiff, reasonably relied upon Defendants' implied warranty for the Physiomesh.

113. The Physiomesh reached consumers without substantial change in the condition in which it was designed, manufactured, tested, trained, marketed, promoted, packaged, labeled, and/or sold by Defendants.

114. As a direct and proximate result of Defendants' conduct, Plaintiff suffered medical complications that included but were not limited to pain and suffering, disability, permanent scarring, mental anguish, loss of capacity for enjoyment of life, lost wages, loss of net accumulations, expenses of hospitalization, extensive medical and nursing care and treatment in the past and in the future, and aggravations of pre-existing medical conditions.

WHEREFORE, as a result of the acts and omissions and conduct of Defendants Johnson and Johnson, Inc. and Ethicon, Inc. as set forth herein, Plaintiff Mary Nimmons is entitled to recover for her personal injuries; past, present, and future medical and related expenses; and past,

present and future mental and physical pain and suffering; Plaintiff should be awarded punitive damages; and Plaintiff should recover any other relief, monetary or equitable, to which they are entitled as against Defendants jointly and severally.

Plaintiff further demands trial by jury for all causes of action detailed herein, judgment against Defendants, jointly and severally, for compensatory and punitive damages, as well as costs, attorney fees, interest, and any other relief, monetary or equitable, to which they are entitled.

BAMBERG LEGAL, LLC

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June 14, 2017
Bamberg, South Carolina